Malcolm Grow Medical Clinic
1050 W. Perimeter Street
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Final Report

The AMIGO Clinical Study: Attrition rates among Military beneficiaries undergoing Intensive Group Outpatient pre-diabetes care

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14. ABSTRACT

This document is the Final Report of the AMIGO Clinical Study: Attrition rates among Military beneficiaries undergoing Intensive Group Outpatient pre-diabetes care funded by AFMSA SG5I. This Final Report discusses the challenges that led to the early closure of the study along with lessons learned and future recommendations. The purpose of this study was to decrease the incidence of progression from pre-diabetes to diabetes by evaluating the impact a lifestyle coach has on a pre-diabetic patients' adherence to a lifestyle education program and resultant improvement of lab values associated with their pre-diabetes diagnosis. The hypothesis was that a patient's adherence/completion of a diabetes prevention program and improvement of their pertinent laboratory values would be directly affected by the involvement of a personalized lifestyle coach. The AMIGO study was unable to evaluate the impact a lifestyle coach has on a pre-diabetic patients' adherence to a lifestyle education program and did not reveal any statistical or clinically significant outcomes regarding lab value results of the intervention. It did result in lessons learned and provided a fundamental understanding of exactly what and moreover who is needed for program and study success which may prove to be beneficial for

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AMIGO Clinical Study: **A**ttrition rates among **M**ilitary beneficiaries undergoing **I**ntensive **G**roup **O**utpatient pre-diabetes care.

Samuel Nokuri, MD, Jennifer Dean, MS, Marquita Price, BSN, MSN

INTRODUCTION

Type II diabetes prevention and/or delay of the disease's progression is the platform from which many efforts have been made to improve prevention methods and decrease disease incidence worldwide. With these efforts researchers have characterized Type II diabetes as a condition most often facilitated by a pre-existing genetic disposition. Further, inactivity and obesity have been observed to serve as catalysts to hasten disease progression.[1,2] A worldwide epidemic, the treatment of this disease has far reaching cost and complications. The military health care system is not absolved of this burden. Various studies examining U.S. military populations report incidence of all types of diabetes reflects that seen in the civilian sector, approximately 2 cases per 1000 patients for all types of diabetes diagnosis. For this reason, diabetes care among active duty, retiree, and their beneficiaries has perpetuated a cyclic burden on the military health system. The burden presents a strain on current healthcare budgets and resources while fueling future charges of decline in military enlistment due to lack of military readiness.[3,4] To address this rising trend, efforts to prevent or delay the onset of type 2 diabetes are intensifying across all branches of service. Once such program, derived from the multi-center diabetes prevention study, the Diabetes Prevention Project, is the Group Lifestyle Balance Program (GLBP). Previously detailed and studied elsewhere, the GLBP, rooted in weight loss and increased physical activity, has proven to reduce the incidence of Type 2 diabetes onset.[5,6] This study will further examine this preventive method within a military population and attempt

to provide a fundamental understanding of exactly what and moreover who is needed for program success and patient adherence in a military treatment facility.

The purpose of this study was to decrease the incidence of progression from pre-diabetes to diabetes by evaluating the impact a lifestyle coach has on a pre-diabetic patients' adherence to a lifestyle education program and resultant improvement of lab values associated with their pre-diabetes diagnosis. The hypothesis was that a patient's adherence/completion of a diabetes prevention program and improvement of their pertinent laboratory values would be directly affected by the involvement of a personalized lifestyle coach.

METHOD

This randomized clinical trial was designed to use standard of care laboratory values (i.e., fasting glucose, hemoglobin A1c, lipid panel, blood pressure, weight and waist circumference) to detect statistically significant differences among groups as a result of the presence or absence of a personalized lifestyle coach. A lifestyle coach may be any medical professional (e.g., RN, exercise physiologist, LPN, medical technician, etc.) who has received specialized training to teach the GLBP. This specialized training is offered by the University of Pittsburgh's Diabetes Institute, the originators of the GLBP, and consists of a two-day workshop which focuses on the theory and "real world" application of pre-diabetes care and the GLBP applications and implementations. Research staff attended the GLBP course. Current standard of care practice for patients empanelled to Malcolm Grow Medical Center and Surgery Center (MGMCSC) are initial (baseline/screening), 3, and 6 months. Further, the attrition rate of enrolled patients was also monitored for noticeable differences in those patients who were randomized to receive a personalized lifestyle coach and those who were not.

This study was designed around a standard of care (SOC) practice. All patients at MGMCSC were referred by their primary care physician to the GLBP as part of their ongoing clinical care. Referrals to the GLBP were also made by the patient's specialist or attending physician. A criteria of SOC GLBP referrals is laboratory values less than one month old. In the event a patient was referred to the GLBP and did not have lab sets less than one month old, those sets were ordered by their primary care physician as part of SOC practice. Screening patients for the AMIGO study took advantage of this SOC practice. Since all patients referred to the GLBP were screened for program eligibility through recent laboratory values, patients were inherently pre-screened for the AMIGO study. The GLBP class was approached by the research coordinator during the introduction session of the GLBP class to determine whether they were interested in participating in the study. The study staff then met individually with those subjects interested in participating in the study to execute informed consent and study enrollment. Once consent was obtained, the study staff more closely examined the medical record for study specific inclusion/exclusion criteria. The Primary Investigator (PI) and any primary care providers referring patients to the GLB did not consent patients. Consent was only performed by study staff (i.e., research coordinator) to avoid any coercion or undue influence to participate in the study. Once consented, a more thorough examination of their medical record was performed to further identify those prime candidates for study participation.

Upon enrollment, patients were randomized into one of two groups and assigned a unique study code that was not part of their social security number. Patients were either assigned to the control group or the experimental group. Randomization was performed by a designated person on the study staff. Control group patients received standard practice GLBP instruction. Experimental group patients received standard practice GLBP instruction plus a personal

lifestyle coach. Once patients were classified in their respective groups they were randomly scheduled in the GLBP sessions.

GLB CD-ROM Prevention Program Lesson Plans and Schedules:

The GLB CD-ROM is a series of taped sessions of staged GLB group classroom sessions to be viewed at home and using provided program materials. GLB CD-ROM covers all of the sessions of the GLBP.[6] Patients randomized to the control group followed the program below:

Week 1: Visit 1 (Group session1)

- Program orientation and welcome.
- Measurement of blood pressure (BP) and baseline anthropometric measurements (height, weight, waist circumferences, and BMI)
- Review of GLB CD-ROM, patient responsibilities, and curriculum
- Distribution of patient materials: GLB CD-ROM#1 (session 1-4), 3 ring binders, session 1-4 handouts, a Calorie King book, measuring cups and spoons for measuring food portions
- Patients will be advised of their goal weight, 7% loss of their total body weight.
- Patients will be tasked to weigh themselves twice weekly, watch the GLB CD-ROM, 1 session per week, preferably at the beginning of the week, and keep daily food logs according to the program.
- Patient phone numbers will be obtained and the next weekly phone call will be scheduled for follow-up.

Week 2 Telephone call #1

Inquire regarding weight measurements, food logs, and home body weights and encouragement to view appropriate session on the CD-ROM.

Week 3 Telephone call #2

Patients should have completed session, "Being a fat and Calorie Detective" and will be asked about their session, weight measurements, and food logs. Lifestyle coaches will also discuss calorie counter to measure food. Patient will be asked about identification of 5 high fat foods and /or one-way to choose less fat and fewer calories as described in the sessions.

Week 4 Telephone call #3

Patients should have completed session3: "Healthy Eating" and will be asked about their session, weight measurements, food logs, and activity chosen as well as discuss changes made to approximate the food pyramid as explained in the session. Patient will be reminded about the upcoming group sessions.

Week 5: Visit 2 (Group session2)

Patients should have completed the CD-ROM session 4: "Move those Muscles". Weights will be recorded, food and activity logs reviewed. The lifestyle coaches will facilitate group discussions about what changes patients have made so far in terms of food intakes and activities. They will also discuss the success and challenges in making those changes. Patients will get the CD-ROM #2(session 5-8), and session 5-8 handouts.

Week 6 Telephone call #4

Patients should have completed session 5:" Tip the Calorie balance". They will be asked about their session and weight measurements, activity and food logs. They will also be asked about the activity chosen and the goals of activity (e.g. How many minutes (60-90min minimum)). Lifestyle coaches will also discuss incorporating activity into lifestyle and ask about the calorie measurements during food intake.

Week 7 Telephone call #5

Patients should have completed session 6: “Take charge of what’s around you”, and will be asked about their session, weight measurements, and food logs. Activity chosen and the goals of activity (e.g. How many minutes (120 min minimum)) will be discussed. Lifestyle coaches will also discuss positive and negative cues surrounding eating.

Week 8 Telephone call #6

Patients should have completed session 7: “Problem Solving”. They will be asked about their session, weight measurements, and food logs as well as activity chosen and the goals of the activity (e.g. How many minutes (150 min minimum)). Lifestyle coaches will also discuss the problems and challenges, “links in the chain”, and identify alternatives.

Week 9: Visit 3 (Group session3)

Patients should have completed session 8:” The keys to Healthy Eating Out”. The lifestyle coaches will record the patients’ weights, and review food and activity logs. The lifestyle coaches will facilitate group discussions of what dietary changes have been made so far, including strategies for eating out. They will also address activities so far and achieving weight and activity goals. Patients will be provided with a pedometer and instructions for use. Lifestyle coaches will also discuss the successes and challenges of the program so far and suggest strategies to improve progress. Patients will get the CD-ROM #3(session 9-12), and session 9-2 hand outs and pedometer.

Week 10 Telephone call #7

Patients should have completed session 9: “The slippery Slope of Lifestyle Changes”. The lifestyle coaches will ask about their session, weight measurements, and food logs, as well as activity chosen and the goals of activity (how many minutes (150min Minimum). The lifestyle

coaches will ask about steps recorded on the pedometers. They will also discuss the "slips" identified surrounding activities and eating.

Week 11 Telephone call #8

Patients should have completed session 10: "Jump Start Your Activity Plan". The lifestyle coaches will ask about their session, weight measurements, and food logs. They will also discuss activity chosen and the goals of activity (how many minutes (150min Minimum). The lifestyle coaches will ask about steps recorded on the pedometers.

Week 11 Telephone call #9

Patients should have completed session 11: "Make Social Cues Work for you". The lifestyle coaches will ask about their session, weight measurements, and food logs as well as activity chosen and the goals of activity (how many minutes (150min Minimum). The lifestyle coaches will ask about steps recorded on the pedometers and discuss strategies for social gatherings and vacations.

Week 12: Visit 4 (Group session4)

Patients should have completed session 12: "Ways to Stay Motivated". The lifestyle coaches will record weights, review food and activity logs. Blood pressure will be measured as well. The lifestyle coaches will facilitate group discussion about the success of the program including lifestyle goals achieved. They will also address future activity goals and strategies, as well as weight goals and strategies. They will offer support to continue the life style changes. Patients will be given a certificates and support group information.

At the end of 12 weeks, study subjects were asked to go to the lab to perform SOC labs (fasting glucose, A1c, lipid profile).

The aforementioned procedural schedule was administered to the experimental group with the addition of increased lifestyle coach involvement. Increased patient encounters included but were not limited to:

- Weekly exercise training sessions
- Biweekly phone calls for the duration of the study
- One-on-one dietary counseling

Both groups of patients (control group and experimental group) were followed for an additional 12 weeks for motivation to continue their lifestyle changes. Patients were followed-up via telephone calls at weeks 16 and 20. At week 24, the patients were asked to repeat their SOC labs.

PARTICIPANTS

Subjects were male and female military health care beneficiaries aged 18-65, selected from participants enrolled in the GLBP, a 12-week prevention program designed to educate patients on lifestyle modifications imperative to the prevention of diabetes. Patients were referred for participation in the GLBP class by his/her physician or self-referred.

Inclusion Criteria:

- Men and women ≥18-65
- Men and women of any ethnicity
- Pre-diabetes diagnosis presenting as:

  BMI ≥25 kg/m2 and fasting glucose ≥100 mg/dL and <126mg/dL)

  AND/OR

  Metabolic Syndrome presenting as a BMI ≥ 25 kg/m2, with at least 3 of the following risk factors for metabolic syndrome: waist circumference (>40 inches men, >35 inches

women); blood pressure ≥130 mmHg (systolic) or ≥85 mmHg (diastolic) OR history of diagnosed hypertension; Low HDL level (<40mg/dL men, <50 mg/dL women); elevated triglyceride level ≥150 mg/Dl:Fasting glucose ≥100mg/dL and <126mg/dL

- Tricare beneficiary

Exclusion Criteria:

- Previous diabetes or diabetes diagnosed as a result of the screening
- Age <18 years old
- Women who are currently (or within past 6-weeks) pregnant or lactating
- Patients with untreated hypothyroidism or previously diagnosed Cushing's syndrome
- Patients currently taking metformin or thiazolidinediones in the previous 12 months
- Patients undergoing any type of medical weight loss regimen
- Any patient deemed by their physician not to be a candidate
- Any patient being treated for major medical conditions that may prevent participation (e.g., severe renal or liver dysfunction, cancer, severe cardiovascular disease)
- Any patient unable to commit to study time frame
- Any patient who is unable to provide informed consent
- Any patient unable to read or write English

MATERIALS

Materials included GLBP CD-ROM kits.

PROCESS

Data sources for this study included the following: (1) data collected from medical records documenting the GLB-CD ROM and (2) study patients' electronic medical record including lab results. Patients enrolled in the study were assigned a unique numeric code that

was not linked to the patient's social security number, but corresponded to enrollment date and sequence. Only records or database entries in existence at the time of study approval were examined in this study. All data was recorded by the investigator and/or study team such that study patients could not be identified directly through identifiers or codes linked to the subjects. All blood samples kept a MGMCSC were handled and disposed of in accordance with federal regulations.

The preventionist entered all data and patient information collected during the group session visits and telephonic calls into an electronic GLBP database. The database contained recorded baseline and interval labs including fasting glucose, hemoglobin A1c, and lipid panel. Additionally, height, weight, waist circumference, BMI, family history of diabetes and gestational diabetes, prior dietary habits, blood pressure and physical activity were recorded. The MGMCSC PI and study staff processed all data collected and statistical analysis was independently performed by a statistician at Wilford Hall Ambulatory Surgical Center (WHASC).

RESULTS

Our hypothesis was that a patient's adherence/completion of a diabetes prevention program and improvement of their pertinent laboratory values would be directly affected by the involvement of a personalized lifestyle coach. The limited data obtained from the study did not provide sufficient results to support this hypothesis. During the turnover of staff the research database malfunctioned and the data was irretrievable. The systems personnel who created the database were no longer employed by the facility. The data had to be repopulated through medical chart reviews during the last three months of the study. During this data re-entry it was discovered that only 22 of the 36 enrolled subjects met the inclusion criteria and 8 were lost to

follow up having only attended the initial session at which they signed their informed consent. There were only 14 patients in the study to submit data for statistical analysis with 50% of those subjects attending three or more of the four classes. The WHASC statistician was unable to compute any real statistical analysis due to the limited data available. The limited data also did not lend itself for clinical significance analysis. RM Anovas was computed which yielded multiple t-tests comparing the two groups at the different time points. The end results were not statistically significant ($p=0.75$). A Chi-square test was also performed which confirmed there was not a statistically significant outcome based on data sets ($p<0.49$).

DISCUSSION

Although this study yielded minimal results previous research has shown a potential cost and time savings in medical care and staffing which may then be may be translated toward the greater military mission. This study was unable to show the direct impact of a lifestyle coach on a patient's adherence or completion of a diabetes prevention program but it did achieve one of its aims, to examine what was needed for program success. This study identified that a successful program requires a full-time staff for recruitment, to provide education and early intervention for patients diagnosed with pre-diabetes and to conduct thorough evaluation and follow up.

There were several contributing factors identified that led to the study not meeting its intended goal. Study enrollment was terminated early due to lack of program and research staffing. The exercise physiologist and research coordinator were lost to funding shortage. There was also a significant staff transition due to change of jobs and retirement for the military component of the research staff to include Chief of the Medical Staff oversight and administrative support. Overall more than 60% of the original staff was lost. These turnovers affected the implementation of the study as initially designed. The PI was tasked with the

additional duty as the Medical Director of Internal Medicine during a staffing shortage. These competing taskers from the Military Treatment Facility (MTF) made it difficult for the PI to fully dedicate and oversee implementation of the research and enrollment of subjects into the research study. An Associate Investigator (AI) was only assigned during the last four months of the study. There were also challenges with recruiting patients based on the provider referral method. Although the research staff were embedded within the primary care clinic there was still an under enrollment into the program. This resulted in an IRB approved target enrollment decrease from 150 to 108, which was still not met. Other than engaging providers directly, advertisement consisted of briefings at professional staff and executive committee meetings. There were also issues with data collection. During the turnover of staff the research database malfunctioned and the data was irretrievable due to personnel who created the database no longer being employed by the facility. It was during this re-entry of data and review of records that it was noted that only 61% of the patients enrolled in the study met inclusion criteria and 36% of those meeting inclusion criteria were lost to follow up having only attended the initial session. Of the 14 remaining subjects only 50% attended more than 75% of the program. The WHASC statistician was unable to compute any real statistical analysis due to the limited data available. The limited data also did not lend itself for clinical significance analysis.

There were several lessons learned and recommendations for future research gleaned from this research study. Retention of staff in key areas of the study is imperative for survival and success. If the PI is an empanelled provider who performs routine patient care, it would be preferable to have an AI who is a non-provider to act without reservation, provide project oversight and quality assurance, and to hold routine meetings to ensure adequate feedback and communication with all stakeholders (research staff, clinic leadership, AFMSA SG5I, etc.) in the

absence of the PI. Additional methods must be used for patient recruitment to include gaining and captivating the interest of primary care teams since their support is pivotal to increasing the subject pool, garnering leadership support, and exploring alternate means for advertisement to include presentations at appropriate staff and executive meetings. The institution of a detailed matrix with back up data storage and ensuring several individuals have access to the databases is necessary for accurate and timely data collection and collation.

The AMIGO study was unable to evaluate the impact a lifestyle coach has on a pre-diabetic patients' adherence to a lifestyle education program and did not reveal any statistical or clinically significant outcomes regarding lab value results of the intervention. It did result in lessons learned and provided a fundamental understanding of exactly what and moreover who is needed for program and study success which may prove to be beneficial for future researchers.

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INTRODUCTION

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METHOD

This randomized clinical trial was designed to use standard of care laboratory values (i.e., fasting glucose, hemoglobin A1c, lipid panel, blood pressure, weight and waist circumference) to detect statistically significant differences among groups as a result of the presence or absence of a personalized lifestyle coach. A lifestyle coach may be any medical professional (e.g., RN, exercise physiologist, LPN, medical technician, etc.) who has received specialized training to teach the GLBP. This specialized training is offered by the University of Pittsburgh's Diabetes Institute, the originators of the GLBP, and consists of a two-day workshop which focuses on the theory and "real world" application of pre-diabetes care and the GLBP applications and implementations. Research staff attended the GLBP course. Current standard of care practice for patients empanelled to Malcolm Grow Medical Center and Surgery Center (MGMCSC) are initial (baseline/screening), 3, and 6 months. Further, the attrition rate of enrolled patients was also monitored for noticeable differences in those patients who were randomized to receive a personalized lifestyle coach and those who were not.

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lifestyle coach. Once patients were classified in their respective groups they were randomly scheduled in the GLBP sessions.

GLB CD-ROM Prevention Program Lesson Plans and Schedules:

The GLB CD-ROM is a series of taped sessions of staged GLB group classroom sessions to be viewed at home and using provided program materials. GLB CD-ROM covers all of the sessions of the GLBP.[6] Patients randomized to the control group followed the program below:

Week 1: Visit 1 (Group session1)

- Program orientation and welcome.
- Measurement of blood pressure (BP) and baseline anthropometric measurements (height, weight, waist circumferences, and BMI)
- Review of GLB CD-ROM, patient responsibilities, and curriculum
- Distribution of patient materials: GLB CD-ROM#1 (session 1-4), 3 ring binders, session 1-4 handouts, a Calorie King book, measuring cups and spoons for measuring food portions
- Patients will be advised of their goal weight, 7% loss of their total body weight.
- Patients will be tasked to weigh themselves twice weekly, watch the GLB CD-ROM, 1 session per week, preferably at the beginning of the week, and keep daily food logs according to the program.
- Patient phone numbers will be obtained and the next weekly phone call will be scheduled for follow-up.

Week 2 Telephone call #1

Inquire regarding weight measurements, food logs, and home body weights and encouragement to view appropriate session on the CD-ROM.

Week 3 Telephone call #2

Patients should have completed session, "Being a fat and Calorie Detective" and will be asked about their session, weight measurements, and food logs. Lifestyle coaches will also discuss calorie counter to measure food. Patient will be asked about identification of 5 high fat foods and /or one-way to choose less fat and fewer calories as described in the sessions.

Week 4 Telephone call #3

Patients should have completed session3: "Healthy Eating" and will be asked about their session, weight measurements, food logs, and activity chosen as well as discuss changes made to approximate the food pyramid as explained in the session. Patient will be reminded about the upcoming group sessions.

Week 5: Visit 2 (Group session2)

Patients should have completed the CD-ROM session 4: "Move those Muscles". Weights will be recorded, food and activity logs reviewed. The lifestyle coaches will facilitate group discussions about what changes patients have made so far in terms of food intakes and activities. They will also discuss the success and challenges in making those changes. Patients will get the CD-ROM #2(session 5-8), and session 5-8 handouts.

Week 6 Telephone call #4

Patients should have completed session 5:" Tip the Calorie balance". They will be asked about their session and weight measurements, activity and food logs. They will also be asked about the activity chosen and the goals of activity (e.g. How many minutes (60-90min minimum)). Lifestyle coaches will also discuss incorporating activity into lifestyle and ask about the calorie measurements during food intake.

Week 7 Telephone call #5

Patients should have completed session 6: “Take charge of what’s around you”, and will be asked about their session, weight measurements, and food logs. Activity chosen and the goals of activity (e.g. How many minutes (120 min minimum)) will be discussed. Lifestyle coaches will also discuss positive and negative cues surrounding eating.

Week 8 Telephone call #6

Patients should have completed session 7: “Problem Solving”. They will be asked about their session, weight measurements, and food logs as well as activity chosen and the goals of the activity (e.g. How many minutes (150 min minimum)). Lifestyle coaches will also discuss the problems and challenges, “links in the chain”, and identify alternatives.

Week 9: Visit 3 (Group session3)

Patients should have completed session 8:” The keys to Healthy Eating Out”. The lifestyle coaches will record the patients’ weights, and review food and activity logs. The lifestyle coaches will facilitate group discussions of what dietary changes have been made so far, including strategies for eating out. They will also address activities so far and achieving weight and activity goals. Patients will be provided with a pedometer and instructions for use. Lifestyle coaches will also discuss the successes and challenges of the program so far and suggest strategies to improve progress. Patients will get the CD-ROM #3(session 9-12), and session 9-2 hand outs and pedometer.

Week 10 Telephone call #7

Patients should have completed session 9: “The slippery Slope of Lifestyle Changes”. The lifestyle coaches will ask about their session, weight measurements, and food logs, as well as activity chosen and the goals of activity (how many minutes (150min Minimum). The lifestyle

coaches will ask about steps recorded on the pedometers. They will also discuss the "slips" identified surrounding activities and eating.

Week 11 Telephone call #8

Patients should have completed session 10: "Jump Start Your Activity Plan". The lifestyle coaches will ask about their session, weight measurements, and food logs. They will also discuss activity chosen and the goals of activity (how many minutes (150min Minimum). The lifestyle coaches will ask about steps recorded on the pedometers.

Week 11 Telephone call #9

Patients should have completed session 11: "Make Social Cues Work for you". The lifestyle coaches will ask about their session, weight measurements, and food logs as well as activity chosen and the goals of activity (how many minutes (150min Minimum). The lifestyle coaches will ask about steps recorded on the pedometers and discuss strategies for social gatherings and vacations.

Week 12: Visit 4 (Group session4)

Patients should have completed session 12: "Ways to Stay Motivated". The lifestyle coaches will record weights, review food and activity logs. Blood pressure will be measured as well. The lifestyle coaches will facilitate group discussion about the success of the program including lifestyle goals achieved. They will also address future activity goals and strategies, as well as weight goals and strategies. They will offer support to continue the life style changes. Patients will be given a certificates and support group information.

At the end of 12 weeks, study subjects were asked to go to the lab to perform SOC labs (fasting glucose, A1c, lipid profile).

The aforementioned procedural schedule was administered to the experimental group with the addition of increased lifestyle coach involvement. Increased patient encounters included but were not limited to:

- Weekly exercise training sessions
- Biweekly phone calls for the duration of the study
- One-on-one dietary counseling

Both groups of patients (control group and experimental group) were followed for an additional 12 weeks for motivation to continue their lifestyle changes. Patients were followed-up via telephone calls at weeks 16 and 20. At week 24, the patients were asked to repeat their SOC labs.

PARTICIPANTS

Subjects were male and female military health care beneficiaries aged 18-65, selected from participants enrolled in the GLBP, a 12-week prevention program designed to educate patients on lifestyle modifications imperative to the prevention of diabetes. Patients were referred for participation in the GLBP class by his/her physician or self-referred.

Inclusion Criteria:

- Men and women ≥18-65
- Men and women of any ethnicity
- Pre-diabetes diagnosis presenting as:

  BMI ≥25 kg/m2 and fasting glucose ≥100 mg/dL and <126mg/dL)

  AND/OR

  Metabolic Syndrome presenting as a BMI ≥ 25 kg/m2, with at least 3 of the following risk factors for metabolic syndrome: waist circumference (>40 inches men, >35 inches

women); blood pressure ≥130 mmHg (systolic) or ≥85 mmHg (diastolic) OR history of diagnosed hypertension; Low HDL level (<40mg/dL men, <50 mg/dL women); elevated triglyceride level ≥150 mg/Dl:Fasting glucose ≥100mg/dL and <126mg/dL

- Tricare beneficiary

Exclusion Criteria:

- Previous diabetes or diabetes diagnosed as a result of the screening
- Age <18 years old
- Women who are currently (or within past 6-weeks) pregnant or lactating
- Patients with untreated hypothyroidism or previously diagnosed Cushing's syndrome
- Patients currently taking metformin or thiazolidinediones in the previous 12 months
- Patients undergoing any type of medical weight loss regimen
- Any patient deemed by their physician not to be a candidate
- Any patient being treated for major medical conditions that may prevent participation (e.g., severe renal or liver dysfunction, cancer, severe cardiovascular disease)
- Any patient unable to commit to study time frame
- Any patient who is unable to provide informed consent
- Any patient unable to read or write English

MATERIALS

Materials included GLBP CD-ROM kits.

PROCESS

Data sources for this study included the following: (1) data collected from medical records documenting the GLB-CD ROM and (2) study patients' electronic medical record including lab results. Patients enrolled in the study were assigned a unique numeric code that

was not linked to the patient's social security number, but corresponded to enrollment date and sequence. Only records or database entries in existence at the time of study approval were examined in this study. All data was recorded by the investigator and/or study team such that study patients could not be identified directly through identifiers or codes linked to the subjects. All blood samples kept a MGMCSC were handled and disposed of in accordance with federal regulations.

The preventionist entered all data and patient information collected during the group session visits and telephonic calls into an electronic GLBP database. The database contained recorded baseline and interval labs including fasting glucose, hemoglobin A1c, and lipid panel. Additionally, height, weight, waist circumference, BMI, family history of diabetes and gestational diabetes, prior dietary habits, blood pressure and physical activity were recorded. The MGMCSC PI and study staff processed all data collected and statistical analysis was independently performed by a statistician at Wilford Hall Ambulatory Surgical Center (WHASC).

RESULTS

Our hypothesis was that a patient's adherence/completion of a diabetes prevention program and improvement of their pertinent laboratory values would be directly affected by the involvement of a personalized lifestyle coach. The limited data obtained from the study did not provide sufficient results to support this hypothesis. During the turnover of staff the research database malfunctioned and the data was irretrievable. The systems personnel who created the database were no longer employed by the facility. The data had to be repopulated through medical chart reviews during the last three months of the study. During this data re-entry it was discovered that only 22 of the 36 enrolled subjects met the inclusion criteria and 8 were lost to

follow up having only attended the initial session at which they signed their informed consent. There were only 14 patients in the study to submit data for statistical analysis with 50% of those subjects attending three or more of the four classes. The WHASC statistician was unable to compute any real statistical analysis due to the limited data available. The limited data also did not lend itself for clinical significance analysis. RM Anovas was computed which yielded multiple t-tests comparing the two groups at the different time points. The end results were not statistically significant ($p=0.75$). A Chi-square test was also performed which confirmed there was not a statistically significant outcome based on data sets ($p<0.49$).

DISCUSSION

Although this study yielded minimal results previous research has shown a potential cost and time savings in medical care and staffing which may then be may be translated toward the greater military mission. This study was unable to show the direct impact of a lifestyle coach on a patient's adherence or completion of a diabetes prevention program but it did achieve one of its aims, to examine what was needed for program success. This study identified that a successful program requires a full-time staff for recruitment, to provide education and early intervention for patients diagnosed with pre-diabetes and to conduct thorough evaluation and follow up.

There were several contributing factors identified that led to the study not meeting its intended goal. Study enrollment was terminated early due to lack of program and research staffing. The exercise physiologist and research coordinator were lost to funding shortage. There was also a significant staff transition due to change of jobs and retirement for the military component of the research staff to include Chief of the Medical Staff oversight and administrative support. Overall more than 60% of the original staff was lost. These turnovers affected the implementation of the study as initially designed. The PI was tasked with the

additional duty as the Medical Director of Internal Medicine during a staffing shortage. These competing taskers from the Military Treatment Facility (MTF) made it difficult for the PI to fully dedicate and oversee implementation of the research and enrollment of subjects into the research study. An Associate Investigator (AI) was only assigned during the last four months of the study. There were also challenges with recruiting patients based on the provider referral method. Although the research staff were embedded within the primary care clinic there was still an under enrollment into the program. This resulted in an IRB approved target enrollment decrease from 150 to 108, which was still not met. Other than engaging providers directly, advertisement consisted of briefings at professional staff and executive committee meetings. There were also issues with data collection. During the turnover of staff the research database malfunctioned and the data was irretrievable due to personnel who created the database no longer being employed by the facility. It was during this re-entry of data and review of records that it was noted that only 61% of the patients enrolled in the study met inclusion criteria and 36% of those meeting inclusion criteria were lost to follow up having only attended the initial session. Of the 14 remaining subjects only 50% attended more than 75% of the program. The WHASC statistician was unable to compute any real statistical analysis due to the limited data available. The limited data also did not lend itself for clinical significance analysis.

There were several lessons learned and recommendations for future research gleaned from this research study. Retention of staff in key areas of the study is imperative for survival and success. If the PI is an empanelled provider who performs routine patient care, it would be preferable to have an AI who is a non-provider to act without reservation, provide project oversight and quality assurance, and to hold routine meetings to ensure adequate feedback and communication with all stakeholders (research staff, clinic leadership, AFMSA SG5I, etc.) in the

absence of the PI. Additional methods must be used for patient recruitment to include gaining and captivating the interest of primary care teams since their support is pivotal to increasing the subject pool, garnering leadership support, and exploring alternate means for advertisement to include presentations at appropriate staff and executive meetings. The institution of a detailed matrix with back up data storage and ensuring several individuals have access to the databases is necessary for accurate and timely data collection and collation.

The AMIGO study was unable to evaluate the impact a lifestyle coach has on a pre-diabetic patients' adherence to a lifestyle education program and did not reveal any statistical or clinically significant outcomes regarding lab value results of the intervention. It did result in lessons learned and provided a fundamental understanding of exactly what and moreover who is needed for program and study success which may prove to be beneficial for future researchers.

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